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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,996	02/28/2002	Brian Leyland-Jones	3298.1003-000	2676

21005 7590 08/10/2004

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,996	LEYLAND-JONES, BRIAN	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/28/02*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-40, and 85-87, drawn to a method of characterizing a multi-determinant metabolic phenotype for a class of N- (aryl substituted) – naphthalidimide compounds, classified in class 424, subclass 9.2.

II. Claims 41-46, drawn to a method of using a multi-determinant metabolic phenotype to individual a treatment regimen and a method of treating an individual having a condition treatable with a class of N- (aryl substituted) – naphthalidimide compounds, classified in class 424, subclass 1.65.

III. Claims 47-55 and 88, drawn to an assay system, classified in class 435, subclass 287.2.

IV. Claims 56-64, drawn to a method using an enzyme-specific assay for the individualization of treatment with a class of N- (aryl substituted) – naphthalidimide compounds, classified in class 435, subclass 7.92.

V. Claims 65-67, drawn to a method of screening a plurality of individuals for participation in a drug treatment trial, classified in class 436, subclass 55.

VI. Claims 68-77, drawn to a method of screening a plurality of individuals for treatment with a class of N- (aryl substituted) – naphthalidimide compounds, classified in class 435, subclass 6.

VII. Claims 78-84, drawn to a method of screening a plurality of individuals for participation in a drug treatment trial, classified in class 424, subclass 9.1.

2. Inventions I and II are independent and distinct inventions. Invention I is a method of characterizing a multi-determinant metabolic phenotype for a class of N – (aryl substituted) – naphthalidimide compounds whereas Invention II is a method of using a multi-determinant metabolic phenotype to individualize a treatment regimen. Invention II requires a safe and therapeutically effective dose of class of N – (aryl substituted) – naphthalidimide and Invention I does not require this limitation.

3. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention IV, claims 56-64.

4. Inventions I and IV are independent and distinct inventions. Invention I is a method of characterizing a multi-determinant metabolic phenotype for a class of N – (aryl substituted) – naphthalidimide compounds whereas Invention IV is a method using an enzyme-specific assay for the individualization of treatment with class of N – (aryl substituted) – naphthalidimide compounds. Further, Invention IV requires determining a rate of drug metabolism according to the determinants and also requires determining a safe and therapeutically effective dose of the class of N – (aryl substituted) – naphthalidimide compounds and Invention I does not require these limitations. Also,

Invention I requires administering to an individual a probe substrate and Invention IV does not require this limitation.

5. Inventions I and V are independent and distinct inventions. Invention I is a method of characterizing a multi-determinant metabolic phenotype for a class of N – (aryl substituted) – naphthalidimide compounds whereas Invention V is a method of screening a plurality of individuals for participation in a drug treatment trial. Further, Invention I requires administering to an individual a probe substrate and Invention V does not require this limitation. Invention V requires selecting individuals having a metabolic phenotype characterized as effective for metabolizing the class of N – (aryl substituted) – naphthalidimide compounds and Invention I does not require this limitation.

6. Inventions I and VI are independent and distinct inventions. Invention I is a method of characterizing a multi-determinant metabolic phenotype for a class of N – (aryl substituted) – naphthalidimide compounds whereas Invention VI is a method of screening a plurality of individuals for treatment. Further, Invention I requires administering to an individual a probe substrate and Invention VI does not require this limitation. Invention VI requires the step of genotyping individuals to identify individuals lacking at least one allelic variation and Invention I does not require this limitation.

7. Inventions I and VII are independent and distinct inventions. Invention I is a method of characterizing a multi-determinant metabolic phenotype for a class of N – (aryl substituted) – naphthalidimide compounds whereas Invention VII is a method of screening a plurality of individuals for treatment with a class of N – (aryl substituted) –

naphthalidimide compounds. Further, Invention VII requires the step of genotyping the individuals to identify individuals lacking at least one allelic variation known to prompt toxicity of the class of N – (aryl substituted) – naphthalidimide compounds and Invention I does not require this limitation. Invention I requires administering to an individual a probe substrate and Invention VI does not require this limitation.

8. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention IV, claims 56-64.

9. Inventions II and IV are independent and distinct inventions. Invention IV requires using an enzyme-specific assay and Invention II does not require this limitation. Also, Invention IV requires determining a rate of drug metabolism and Invention II does not require this limitation.

10. Invention II and V are independent and distinct inventions. Invention II is a method of using a multi-determinant metabolic phenotype to individualize a treatment regimen of a class of N – (aryl substituted) – naphthalidimide compounds for an individual whereas Invention V is a method of screening a plurality of individuals for participation in a drug treatment trial assessing the therapeutic effect of a class of N – (aryl substituted) – naphthalidimide compounds. Further, Invention V requires selecting

individuals having a metabolic phenotype characterized as being effective for metabolizing the class of N - (aryl substituted) – naphthalidimide compounds.

11. Inventions II and VI are independent and distinct inventions. Invention II is a method of using a multi-determinant metabolic phenotype to individualize a treatment regimen of a class of N – (aryl substituted) – naphthalidimide compounds for an individual whereas Invention VI is a method of screening a plurality of individuals for treatment with a class of N - (aryl substituted) – naphthalidimide compounds. Further, Invention VI requires the step of genotyping individuals to identify individuals lacking at least one allelic variation and Invention II does not require this limitation.

12. Inventions II and VII are independent and distinct inventions. Invention II is a method of using a multi-determinant metabolic phenotype to individualize a treatment regimen of a class of N – (aryl substituted) – naphthalidimide compounds for an individual whereas Invention VII is a method of screening a plurality of individuals for participation in a drug treatment trial assessing the therapeutic effect of a candidate drug treatment. Further, Invention VII requires the step of genotyping each of the individuals to identify individuals lacking at least one allelic variation known to prompt the toxicity of the drug and Invention II does not require this limitation.

13. Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP §

806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Invention I, claims 1-40 and 85-87.

14. Inventions III and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another materially different process such as the process of Inventions I or IV.

15. Inventions III and VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Inventions I or IV.

16. Inventions III and VII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as the process of Inventions I or IV.

17. Inventions IV and V are independent and distinct inventions. Invention IV is a method of using an enzyme-specific assay for the individualization of treatment with a

class of N – (aryl substituted) – naphthalidimide compounds whereas Invention V is a method of screening a plurality of individuals for participation in a drug treatment trial assessing the therapeutic effect of a class of N – (aryl substituted) – naphthalidimide compounds. Further, Invention V requires selecting individuals having a metabolic phenotype characterized as effective for metabolizing the class of N – (aryl substituted) – naphthalidimide compounds.

18. Inventions IV and VI are independent and distinct inventions. Invention VI requires genotyping individuals to identify individuals lacking at least one allelic variation known to prompt toxicity of N – (aryl substituted) – naphthalidimide compounds and Invention IV does not require this limitation. Further, Invention IV requires treatment with a probe substrate and Invention VI does not require this limitation.

19. Inventions IV and VII are independent and distinct inventions. Invention VII requires genotyping each of the individuals to identify individuals lacking at least one allelic variation known to prompt the toxicity of the drug and Invention IV does not require this limitation.

20. V and VI are independent and distinct inventions. Invention VI requires genotyping individuals to identify individuals lacking at least one allelic variation known to prompt toxicity of N – (aryl substituted) – naphthalidimide compounds and Invention V does not require this limitation.

21. Inventions V and VII are independent and distinct inventions. Invention VII requires genotyping each of the individuals to identify individuals lacking at least one

allelic variation known to prompt the toxicity of the drug and Invention V does not require this limitation.

22. Inventions VI and VII are independent and distinct inventions. Invention VI is a method of screening a plurality of individuals for treatment wit a class of N – (aryl substituted) – naphthalidimide compounds whereas Invention VII is a method of screening a plurality of individuals for participation in a drug treatment trial assessing the therapeutic effect of a candidate drug.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

In the event Applicant elects Group I, claims 1-40 and 85-87 a species election must also be made:

Species 1 *one affinity complexation agent.

Species 2 *one rapid immunoassay technology

Species 3 *one means of detection of the biosensor

Species 1: affinity complexation agent

(i). antibody

(ii). molecular imprinted polymer

(iii). aptmer

(iv). receptor

(v). anticalin

Species 2: rapid immunoassay technology

(i). Rapid Analyte Measurement Platform technology

(ii). light-emitting immunoassay technology

Species 3: means of detection of the biosensor

(i). electrochemical sensor

(ii). optical sensor

(iii). Microgravimetric

Therefore, if applicant elects Group I, Applicant must also elect one affinity complexation agent, one rapid immunoassay technology and one means of detection of the biosensor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7, 15-17, 20 and 26-88 are generic. Claims 8-14, 18, 19 and 21-25 are subject to species election.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
August 6, 2004

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 /641
8/7/04